REMARKS

I. INTRODUCTION

The Office Action mailed on September 22, 2004 and the references cited therein have been carefully studied, and in view of the following representations, reconsideration and allowance of this application are most respectfully requested.

Claims 1-10 are pending in the present application. Claims 6-10 have been withdrawn from consideration, and claims 1-5 have been rejected under 35 U.S.C. § 103. In view of the following remarks, Applicant respectfully submits that the claims are in condition for allowance.

II. REJECTIONS UNDER § 103

Claims 1-5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over: (1) U.S. Patent No. 5,643,201 to Peabody *et al.* ("Peabody *et al.*") in view of U.S. Patent No. 4,668,400 to Veech ("Veech"); (2) U.S. Patent No. 5,542,919 to Simon *et al.* ("Simon *et al.*") in view of Veech; (3) U.S. Patent No. 3,620,215 to Tysk *et al.* ("Tysk *et al.*") in view of Veech; (4) European Patent Application No. 0 149 001 ("EPA 0 149 001") in view of Veech; and (5) U.S. Patent No. 6,409,699 to Ash ("Ash") in view of Veech. It is respectfully submitted that these rejections should be withdrawn for at least the following reasons.

In order for a claim to be rejected for obviousness under 35 U.S.C. § 103(a), not only must the prior art teach or suggest each element of the claim, but the prior art must also suggest combining the elements in the manner contemplated by the claim. *See Northern Telecom, Inc. v. Datapoint Corp.*, 908 F. 2d 931, 934 (Fed. Cir. 1990), *cert. denied* 111 S.Ct. 296 (1990); *In re Bond*, 910 F. 2d 831, 834 (Fed. Cir. 1990). The Examiner bears the initial burden of establishing a *prima facie* case of obviousness. *See* M.P.E.P. §2142. To establish a *prima facie* case of obviousness, the Examiner must show, *inter alia*, that there is some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the references and that, when so modified or combined, the prior art teaches or suggests all of the claim limitations. *See* M.P.E.P. §2143. Applicant respectfully submits that the Examiner has not established a *prima facie* case of obviousness.

Peabody *et al.* is directed to a continuous peritoneal dialysis apparatus. The method described in Peabody *et al.* "includes accumulating a sterilized dialysis fluid in a first reservoir, weighing the dialysis fluid in the first reservoir to determine a first prescribed volume of dialysis fluid, and filling a peritoneal cavity of a patient with the first prescribed volume of dialysis fluid from the first reservoir. Next, the method includes draining the dialysis fluid from the peritoneal cavity of the patient into a second reservoir, weighing the dialysis fluid in the second reservoir to determine a second prescribed volume of dialysis fluid, and terminating the draining of the dialysis fluid from the peritoneal cavity in response to weighing of the second prescribed volume of dialysis fluid in the second reservoir.

The volume of fluid in the peritoneal cavity of the patient is monitored and the amount of dialysis fluid in the peritoneal cavity is adjusted to provide a desired volume in the peritoneal cavity." Peabody *et al.*, col. 5, lines 21-36. However, Peabody *et al.* do not disclose "measuring the concentration of an endogenous substance that passes through a peritoneum into the peritoneal solution in the peritoneal cavity."

Simon *et al.* is directed to a peritoneal dialysis device. The device disclosed in Simon *et al.* "has a balancing chamber that is divided into two halves by a movable, liquid-impermeable wall. The amount of liquid introduced into one half displaces the amount of fluid present in the other half in exact volumetric correspondence by displacement of the wall. As a result of this, the inlet and outlet volume can be determined with high accuracy, with an accuracy of one chamber volume (approx. 1% error), so that the ultrafiltered amount can also be determined accurately too." Simon *et al.*, col. 2, lines 47-55. However, Simon *et al.* do not disclose "measuring the concentration of an endogenous substance that passes through a peritoneum into the peritoneal solution in the peritoneal cavity."

Tysk *et al.* is directed to an apparatus for peritoneal dialysis. Tysk *et al.* discloses "[a]n apparatus for peritoneal dialysis treatment of a patient operating automatically in accordance with a predetermined program comprising a plurality of successive dialysis cycles each consisting of a fill-phase during which fresh dialysis

fluid is introduced into the peritoneal cavity of the patient, a dialysis-phase during which the dialysis fluid remains in the peritoneal cavity, and a drain-phase during which the used dialysis fluid is withdrawn from the peritoneal cavity of the patient." Tysk *et al.*, abstract. However, Tysk *et al.* do not disclose "measuring the concentration of an endogenous substance that passes through a peritoneum into the peritoneal solution in the peritoneal cavity."

EPA 0 149 001 has been described in the background section of the present specification, as EPA 0 149 001 is directed to a peritoneal dialysis device. As described in the present specification, EPA 0 149 001 discloses a peritoneal dialysis device in which the ultrafiltration rate is controlled as a function of the intraperitoneal volume, so that "overfilling" of the patient is precluded, and wherein ultrafiltration control is based on measurement of dilution. The peritoneal dialysis device of EPA 0 149 001 comprises a closed circuit, in which dialyzing fluid circulates and to which a substance is added from outside whose secretion and resorption rate is negligible during the entire duration of treatment. The concentration of this exogenous substance in the peritoneal solution continuously decreases with increasing volume. During treatment, the concentration of this exogenous substance is measured and compared with the initial concentration at the start of treatment. When a difference between the measured concentration and the initial concentration is detected, the ultrafiltration means withdraws fluid from the peritoneal cavity until the initial concentration in the dialyzing fluid has been

reestablished. However, EPA 0 149 001 does not disclose "measuring the concentration of an endogenous substance that passes through a peritoneum into the peritoneal solution in the peritoneal cavity." In fact, as was described in the present specification, a drawback with the device disclosed in EPA 0 149 001 is that an exogenous substance must be added to the dialyzing fluid, and thus, incompatibilities cannot be ruled out. In addition, further secretion or resorption of the exogenous substance in EPA 0 149 001 may also result in defective control of the ultrafiltration rate.

Ash is directed to a continuous flow-through peritoneal dialysis (CFPD) method with control of intraperitoneal pressure. Ash discloses "devices and methods for treating patients suffering from renal insufficiency and/or hepatic insufficiency." Ash, col. 5, line 66 to col. 6, line1. The devices and methods disclosed in Ash "utilize in preferred embodiments the advantageous features of a dual lumen catheter, preferably a T-fluted dual lumen catheter, combined with a substantially constant rate of dialysate inflow and a pressure-dependent outflow controller ...." Ash, col. 6, lines 8-12. According to Ash, the devices and methods disclosed therein "provide[] in certain aspects advantageous systems for passing fluid through a patient's peritoneal cavity at a relatively high flow rate, while maintaining in the peritoneal cavity an optimal dialysate pressure, to thereby alter the contents of the patient's blood by diffusion of molecules through the peritoneal membrane." Ash, col. 6, lines 14-19. However, Ash does not disclose "measuring

the concentration of an endogenous substance that passes through a peritoneum into the peritoneal solution in the peritoneal cavity."

Thus, none of the five primary references cited in the rejections under 35 U.S.C. § 103(a) disclose or suggest "measuring the concentration of an endogenous substance that passes through a peritoneum into the peritoneal solution in the peritoneal cavity," as is currently claimed in independent claim 1. Dependent claims 2-5 each depend, directly or indirectly, from independent claim 1 and thus include this claim limitation as well. As described in the present specification, the method of the present invention is advantageous "in that exogenous substances need not be added. Therefore, determination of the intraperitoneal volume is less cumbersome and less costly. In addition, incompatibilities can be ruled out." Specification, page 3, lines 9-11.

Veech does not cure the shortcomings of Peabody *et al.*, Simon *et al.*, Tysk *et al.*, EPA 0 149 001, and Ash. Veech is generally directed to hemodialysis processes and hemodialysis solutions. Veech allegedly discloses "[t]echniques for predicting the respective concentrations and distributions of diffusible materials in solutions on opposing sides of a semi permeable membrane." Veech, abstract. According to the disclosure of Veech, "the concentrations and distributions of electrolytes in, respectively: (a) the freshly hemodialyzed blood of a patient, and (b) the hemodialysis solution used for the hemodialysis of that patient's blood, are

defined by certain mathematical relationships which closely approximate such concentrations and distributions in each of the hemodialyzed blood and the hemodialysis solution[, which] ... permits one to practice various new and very useful processes in the field of hemodialysis[, such as] ... preparing an aqueous hemodialysis solution which when used for hemodialysis of a given patient will produce in the blood (plasma) being returned to such patient after hemodialysis thereof a desired or predicted composition of electrolytes." Veech, col. 8, lines 33-49. Veech further discloses that "[i]n such a process, one measures the approximate molar concentration of the albumin initially present *in the blood of the patient* to be hemodialyzed with such desired solution." Veech, col. 23, lines 55-58 (emphasis added). As stated in Veech, "[v]arious teohniques [sic] are available for measuring albumin content in mammalian blood and any convenient such technique can be employed in the practice of this invention." Veech, col. 23, lines 58-61. That is, Veech discloses the measuring of albumin content in mammalian blood, rather than the measuring of the concentration of albumin in "the peritoneal solution in the peritoneal cavity" after such albumin has "pass[ed] through a peritoneum." Thus, Veech does not teach nor suggest "measuring the concentration of an endogenous substance that passes through a peritoneum into the peritoneal solution in the peritoneal cavity," as is currently recited in the pending claims.

Thus, neither Peabody *et al.*, Simon *et al.*, Tysk *et al.*, EPA 0 149 001, nor Ash, each in view of Veech, teach or suggest each and every element of the

claimed invention as recited in rejected claims 1-5. Therefore, it is respectfully submitted that the rejections of these claims under 35 U.S.C. § 103 have been overcome and should therefore be withdrawn.

III. CONCLUSION

In light of the foregoing, Applicant respectfully submits that all pending claims are in condition for allowance. Prompt reconsideration and allowance of the present application are therefore earnestly solicited.

Respectfully submitted,
KENYON & KENYON

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By: _____
Kevin T. Godlewski (Reg. No. 47,598)

One Broadway
New York, New York 10004
(212) 425-7200